IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
CHATTANOOGA DIVISION

(UNDER SEAL),	)	
	)	
Plaintiffs/Relators,	)	
	)	**CIVIL ACTION NO.**
v.	)	1:19-cv-38
	)	
(UNDER SEAL),	)	
	)	**JURY DEMAND**
Defendants	)	Phillips/Steger
	)	

FALSE CLAIMS ACT COMPLAINT

[FILED UNDER SEAL]

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
CHATTANOOGA DIVISION

UNITED STATES OF AMERICA, ex rel. Pat Doe, and STATE OF TENNESSEE, ex rel. Pat Doe,	)	
Plaintiffs/Relators,	)	
	)	**CIVIL ACTION NO.**
v.	)	
	)	_____
HCA, INC., HCA, INC. d/b/a PARKRIDGE MEDICAL CENTER, HCA, INC. d/b/a TRISTAR HEALTH SYSTEM, INC. and NEOPHARMA TENNESSEE, LLC f/k/a DR. REDDY'S LABORATORIES LTD. and a/k/a DR. REDDY'S LABORATORIES TENNESSEE, LLC.	)	**JURY DEMAND**
Defendants.	)	

FALSE CLAIMS ACT COMPLAINT

UNDER SEAL

Comes the Relator, under seal by and through their attorneys and on behalf of the United States of America and the State of Tennessee, for his/her Complaint against HCA, Inc., HCA, Inc. d/b/a Parkridge Medical Center, HCA, Inc. d/b/a Tristar Health System, Inc., Neopharma Tennessee, LLC f/k/a Dr. Reddy's Laboratories Ltd. and a/k/a Dr. Reddy's Laboratories Tennessee, LLC, and hereby alleges as follows:

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II. NATURE OF THE CASE

1. The Relator has filed this Complaint under the qui tam provisions of the United States False Claims Act, 31 U.S.C. §§3729, *et seq.* ("FCA"), and under Tennessee's Medicaid False Claims Act, T.C.A. §§71-5-181, *et seq.*, and T.C.A. §§4-18-101, *et seq.,* Tennessee's False Claim Act.

2. The False Claims Act provides, *inter alia*, that any person who knowingly submits a false or fraudulent claim to the federal government for payment or approval is liable to the Government for a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each claim, plus three times the amount of the false claim. 31 U.S.C. §3729(a). Lawsuits brought under the Act may include false claims made within six years of the date of filing. The Act also permits assessment of the civil penalty even without proof of specific damages. *Rex Trailer Co. v. U.S.*, 350 U.S. 148 (1956).

III. PRE-FILING DISCLOSURE

3. Prior to filing this False Claims Act Complaint, the Relator made a pre-filing disclosure of the allegations contained herein to the United States Attorney's Office for the Eastern District of Tennessee. The Relator is, therefore, an original source of the allegations set forth herein.

IV. JURISDICTION AND VENUE

4. Jurisdiction over this action is conferred upon this Court, pursuant to 28 U.S.C. §1331 (federal question), 28 U.S.C. §1345 (United States as Plaintiff), and 31 U.S.C. §3729-3733 (False Claims Act).

5. Additionally, in order to promote judicial efficiency, a federal court may exercise supplemental jurisdiction over claims under Tennessee common law and violations of the

Tennessee Medicaid False Claims Act, T.C.A. §§71-5-181, *et seq.*, and pursuant to 28 U.S.C. §3732(b) and 28 U.S.C. §1367(a), in that all state created claims pled, or that may be pled, in this case arise out of a common nucleus of operative facts.

6. This Court, the United States District Court of the Eastern District of Tennessee, has personal jurisdiction over Defendants pursuant to 31 U.S.C. §3732(a) because Defendants are located and do business in the Eastern District of Tennessee.

7. Venue is proper in the United States District Court for the Eastern District of Tennessee, pursuant to 28 U.S.C. §1391(b) and (c), and 31 U.S.C. §3732(a), because the acts and practices alleged in Relator's Complaint occurred in this District.

V. SUMMARY OF ALLEGATIONS

8. This cause of action arises from the Hospital Corporation of America's Parkridge Medical Center's fraudulent pattern and practice of dispensing a misbranded drug (produced by Neopharma Tennessee, LLC f/k/a Dr. Reddy's Laboratories Ltd. a/k/a Dr. Reddy's Laboratories Tennessee, LLC) to cancer patients at Parkridge Medical Center (hereinafter also referred to as "Parkridge" or "the Hospital"). The volumes of solution listed on medication labels are inaccurate. Each time a label is printed for the medication to be administered to a patient, the number of milligrams of azacitidine is inaccurate, and is therefore "misbranded" according to 31 U.S.C. § 502(a). The drug at issue, azacitidine (from Dr. Reddy's Laboratories) is used for treatment for patients with certain types of cancer. Furthermore, Dr. Reddy's Laboratories continues to manufacture azacitidine, which is impure, contaminated, and misbranded under 31 U.S.C. § 502 (a), in violation of various provisions of volume 21 of the Code of Federal Regulations and directives of the Food and Drug Administration issued in or about February 2008. Dr. Reddy's Laboratories continues to provide azacitidine to Parkridge and all other

hospitals in the HCA system, knowing the same to be misbranded. Many of the patients receiving doses of azacitidine are recipients of Medicare benefits, thus HCA and Dr. Reddy's Laboratories are being paid monies from the United States of America based upon false statements.

9. The problems with the volume and mislabeling are as follows: According to the manufacturer's package insert, the azacitidine is supposed to yield a 10 mg/ml solution. Employees of Parkridge repeatedly found that the azacitidine yields 9 ml or less, meaning that the actual concentration is approximately 11 mg/ml. Therefore, if the treating physician's order is for a 150 mg dose, directions would call for using 15 ml of the 10 mg/ml solution. If they used 15 ml of the 11 mg/ml solution, then the dose dispensed would be 165 mg instead of the 150 mg ordered by the physician. In short, this would lead to a 10% dosing error. When the patient label is placed on the bag, it states 150 mg dose, when in fact it would be a 165 mg dose, or some other amount, as they cannot be exactly sure of the dose amount. This is dispensing a "misbranded" drug pursuant to 31 U.S.C. § 502(a).

10. This is not solely a misbranding issue; it is an issue of patient safety. It is estimated that virtually every patient receiving azacitidine (from Dr. Reddy's Laboratories) for their cancer treatment at Parkridge Medical Center since April 2015 (and possibly before that date) has been overdosed with the drug, as outlined above. Overdosing of a patient can cause azacitidine toxicity or death.

11. Plaintiffs' allegations are further detailed below in Section VIII, under the heading "Substantive Allegations."

VI. THE PARTIES

12. The Relator: Pat Doe, an employee of the Parkridge Medical Center.

13. Defendant HCA, Inc. ("HCA"), is a Delaware Corporation with its principal executive offices located at One Park Plaza, Nashville, Tennessee 37203. Through its Tri Star Health System, Inc., HCA owns and operates Parkridge Medical Center, Inc., at all times relevant to the Complaint herein.

14. Tristar Health System, Inc., with the address of 1 Park Plaza, Nashville, TN, can be served through its registered agent at CT Corporation System, 300 Montvue Road, Knoxville, TN 37919-5546.

15. Neopharma Tennessee, LLC f/k/a Dr. Reddy's Laboratories Ltd. a/k/a Dr. Reddy's Laboratories Tennessee, LLC (also referred to herein as "Dr. Reddy's Laboratories" or "Dr. Reddy's"), with the address of 201 Industrial Drive, Bristol, TN 37620, and can be served through its registered agent at Sesha Chalapati Madireddi, 201 Industrial Drive, Bristol, TN 37620-5413.

VII. SOURCE OF RELATOR'S ALLEGATIONS

16. Relator states that all allegations herein are based on evidence obtained directly by Relator independently and through his/her own labor and efforts. Additionally, the Relator made a pre-filing disclosure to the government of the information contained herein. Relator is therefore, an original source of information within the meaning of the False Claims Act, 31 U.S.C. §3730(c)(4)(B). *See, e.g., U.S. ex. Rel. Antoon v. Cleveland Clinic Foundation, et al.,* 788 F.3d 605 (6th Cir. 2015); *U.S. ex. Rel. Osheroff v. Healthspring, Inc., et al.,* 938 F.Supp.2d 724 (M.D. Tenn. 2013).

VIII. SUBSTANTIVE ALLEGATIONS

A. Parkridge Medical Center has put its cancer patients in danger, by fraudulently dispensing a misbranded drug (produced by Dr. Reddy's Laboratories) in amounts in excess of the doses ordered by their physicians.

17. In or around April 2015, Relator first became aware that there was a problem with the azacitidine from Dr. Reddy's Laboratories. At that time, a Certified Pharmacy Technician employed by Parkridge, was assigned to the chemotherapy hood to compound chemotherapy doses. The Relator learned that she/he was unable to extract the volume of dissolved azacitidine (from Dr. Reddy's Laboratories) to yield the correct volume and dose for the patient. As a result, technicians were instructed to use needleless attachments to the vials. The Relator and other staff destroyed those vials and tried again with two new vials of azacitidine (also from Dr. Reddy's Laboratories). This time, they used needles to inject and extract the solution, having concluded that the needleless system had a small reservoir which did not allow removal of all the dissolved chemotherapy. Again, they were unable to get the needed volume to yield the correct volume and dose for the patient. In the process, they exhausted the Hospital's supply of azacitidine (from Dr. Reddy's Laboratories) and had to borrow Vidaza (azacitidine manufactured by Celgene) from Erlanger Medical Center. The mixing of Vidaza (by Celgene) yielded the correct volume and dose for the patient's treatment. The Pharmacy Operations Manager for Parkridge, Dr. Kyle England, was informed about the errors in volumes with Dr. Reddy's azacitidine. Dr. England failed to take any action to investigate or remedy the problem.

18. In or around June 2015, the Relator and other staff, employed at Parkridge Medical Center, were still experiencing problems with the azacitidine (from Dr. Reddy's Laboratories). Additionally, they discovered another discrepancy with the volume of azacitidine solution. By that time, they had made it standard procedure to avoid using the needleless system

when mixing azacitidine (by Dr. Reddy's Laboratories). Multiple vials were wasted, but after many attempts they were finally able to achieve what appeared to be a 19.5 ml total volume yielded instead of the expected 20 ml. This appeared to be an error of approximately 2.5%. After these continued difficulties, Director of Pharmacy, Dr. Dustin Smith, and Pharmacy Operations Manager, Dr. Kyle England, were informed of the previous incident and the additional difficulties. Director Smith instructed the details to be emailed to him.

19. On June 3, 2015, the Director of Pharmacy, Dr. Dustin Smith, and Pharmacy Operations Manager, Dr. Kyle England, and Clinical Pharmacy Manager, Dr. Rebecca Horne were informed of the aforementioned difficulties with the volume deficit when using the azacitidine (from Dr. Reddy's Laboratories). It was requested that they consider changing back to the Vidaza brand. **Since March of 2015, there has been at least one patient at Parkridge who required treatment for an overdose of azacitidine.**

20. Upon information and belief, Dr. Reddy's Laboratories had been found by the Food and Drug Administration ("the FDA"), to be compromising sterility of the product (including azacitidine), after FDA inspected Dr. Reddy's plant in southern India. An FDA inspection of this facility occurred on March 3, 2015, but the Defendant Dr. Reddy's Laboratories failed, refused and neglected to remedy the process that was rendering the impure drugs.

21. Upon information and belief, based upon FDA reports, Dr. Reddy's Laboratories had been found to be violating various federal statutes, federal regulations and other provisions, policies and procedures, which resulted in the production of the impure azacitidine at this facility in southern India. In spite of the production impurities, Dr. Reddy's Laboratories continued to file statements and certifications with the FDA, certifying their compliance with FDA rules and all relevant and applicable federal statutes, codes, regulations and provisions. In fact, azacitidine

was being produced that was not pure and would not render the appropriate chemical composition, when mixed with pure water, as provided on the enclosed instructions. Upon information and belief, Dr. Reddy's Laboratories had failed to comply with FDA regulations regarding the production of azacitidine from at least January 2013, to the date of filing of this complaint.

22. This fraudulent practice resulted in fraudulent charges to Medicare, TennCare, and other government programs. Furthermore, HCA, Inc., through its agents and employees, at Tri Star and Parkridge, submitted multiple forms and otherwise certified certain information to Medicare, Tenncare and other government programs in order to receive these fraudulent payments.

23. In approximately late March 2016, Dr. Dustin Smith at Parkridge Medical Center determined that the azacitidine manufactured by Dr. Reddy's was not reliable and asked the purchasing group at HCA to find an alternative source. From that date in March 2015 until as late as October 2018, orders by Parkridge and other hospitals in the HCA system for azacitidine with other companies defaulted to being ordered from Dr. Reddy's. The price for azacitidine is cheaper at Neopharma (f/k/a Dr. Reddy's). In addition to accumulating approximately hundreds of millions of dollars in fraudulent charges over a period of six or more years, this fraudulent practice has resulted in thousands of innocent patients receiving inaccurate doses of azacitidine (by Dr. Reddy's Laboratories) while being treated for cancer at Parkridge Medical Center, or other hospitals in the HCA system.

24. Upon information and belief, due to the purchase of azacitidine by HCA through a central purchasing entity, thought to be HealthTrust, all HCA patients at all 168 hospitals in the system have been the subject of the aforementioned fraud for, at least, the last 6 years.

IX. PERTINENT RULES AND REGULATIONS

Dr. Reddy's has violated the following federal regulations, statutes and directives:

1. 21 C.F.R. § 211.192 – Failing to thoroughly investigate any unexplained discrepancy in a batch or components to meet specifications.

2. February 2008 Directive of FDA – Failing to intervene when it was discovered that there was a malfunction in the mechanism to transport the filled vials, compromising the sterility of the product. This lack of adequate investigations is a violation of FDA inspection and directives from its February 2008 inspection.

3. 21 C.F.R. § 211.113(b) – Failing to comply with written procedures designed to prevent microbiological contamination of drug products purporting to be sterile.

4. 21 C.F.R. § 211.100(a) – Failing to establish adequate written procedures for production and process control, designed to prevent microbiological contamination of drug products purporting to be sterile, to ensure that drug products manufactured have the identity, strength, quality, and purity they purport. Nor did Dr. Reddy's Laboratories' quality control unit review and approve these procedures. Furthermore, Dr. Reddy's procedure for qualifying operators to perform visual inspection was unacceptable to the FDA. Nor did Dr. Reddy's indicate how previously inspected products may have been affected by the substandard visual inspection procedures and qualification kits.

5. 21 U.S.C. § 351(a)(2)(B), 21 U.S.C. § 801(a)(3), 21 U.S.C. §381(a)(3) and 31 U.S.C. §501(a)(2)(B) of the Food Drug & Cosmetics Act ("FD&C Act") – the noncomplying doses of azacitidine manufactured and distributed by Dr. Reddy's did not conform to the Current Good Manufacturing Practice ("CGMP") of the FD&C Act.

X. SPECIFIC COUNTS AND PRAYER FOR RELIEF

Wherefore, the Plaintiffs sue the defendants under the authority cited above for violation of the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, Tennessee's Medicaid False Claims Act, TCA §§71 – 5 – 181, *et seq.*, TCA §§4 – 18 – 101, *et seq.*, Tennessee False Claims Act for at least $201,600,000.00, the damages provided therein, proximately caused by the actions or failures of the defendants at all HCA hospitals as specifically set out within this complaint. The plaintiffs further sue for not only the actual amount of monies paid by the United States of America and the State of Tennessee for the administration of doses of azacitidine, but also for penalties of three (3) times the amount of the actual damages, and $5,500-$11,000 per incident of amounts of money paid by the federal government and the State of Tennessee to the defendants herein for said misbranded azacitidine, and that a jury be impaneled to try the issues with this cause.

XI. JURY DEMAND

Respectfully submitted,

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